

the Reporter



Failure to diagnose lung cancer

By Laura Brockway

Case study

A 59-year-old man came to the emergency department with complaints of respiratory problems. His medical history included chronic obstructive pulmonary disease, sleep apnea, chronic bronchitis, emphysema, obesity, and he reported smoking for more than 40 years. A chest x-ray revealed a “possible 1 cm pulmonary nodule superimposed over the anterior end of the left 5th rib,” which was not present on a chest x-ray taken seven months earlier. The radiologist recommended a left rib series, which was not done because the patient left the ED against medical advice. This report was faxed to the patient’s internal medicine physician, the defendant in this case.

The defendant’s partner had his nurse call the patient to inform him of the abnormal chest x-ray and to have him return to the clinic in the near future. This call was not documented in the record, and the practice did not schedule an appointment for the patient. Two months later, the patient came to the ED,

and was hospitalized after a serious episode of respiratory distress. A chest x-ray indicated “a nodular density over the left anterior 5th rib measuring 2.7 cm.” This x-ray report notes the defendant as the ordering physician and was in the patient’s office chart. There was no indication this report was reviewed, and the defendant testified that he did not see the report.

The patient came to the clinic the next month, and was treated for bronchitis by the defendant. Two months later, the patient was re-admitted to the hospital by the defendant’s partner. Differential diagnosis was pneumonia or empyema. A chest x-ray noted “a mass-like infiltrate” measuring 5 cm in diameter, and a repeat film two days later noted “the previously described nodule or mass was totally obscured by pleural effusion.” A CT scan of the chest was ordered. The radiologist noted no discreet mass and he suspected that the mass-like density adjacent to the heart border on earlier films represented some focal lung consolidation or loculated fluid. An empyema of the left chest was drained three days later. X-rays were done twice to confirm chest tube placement. At discharge, the radiologists noted, “moderate opacification remained in the left lung base” but was slightly improved since the previous study.

One month after his hospitalization, the patient was seen by the defendant for respiratory distress. The physician ordered a chest x-ray to rule out pneumonia. That report described an apparent mass-like infiltrate, again seen in the frontal view. According to the radiologist, the lack of change of that focal infiltrate raised the possibility of neoplasm. He recommended a CT scan. Seven days later, the CT scan revealed a “4.5 x 3 cm mixed density mass seen inferior laterally

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in the inferior lingular segment of the left upper lobe abutting the pleural surface.” The radiologist noted that malignant neoplasm along with some associated loculated effusion remained a definite consideration. The patient was referred to a pulmonologist. A biopsy of the lung tissue indicated squamous cell carcinoma. This diagnosis was made approximately seven months after the patient’s first visit to the ED. At last report, he had received multiple courses of chemotherapy.

The patient filed a lawsuit against the internal medicine physician, alleging failure to diagnose lung cancer in a timely manner.

Those representing the defendant felt that causation would be extremely difficult to prove due to the patient’s noncompliance and the presence of comparative negligence (i.e., the patient contributed to his condition by smoking). Physicians who reviewed this case had different opinions about whether an earlier diagnosis of seven months would have made a difference in treatment and prognosis. However, negligence can be implied by the lack of timely follow-up and aggressive action in response to the abnormal chest x-ray report seven months before diagnosis.

The defendant explained that he was too busy to review every report sent to his office, and that he had no system delegating that responsibility to a staff member with guidelines to bring abnormal studies to his attention. Failure to meet the standard of care with regard to timely follow-up on test results, and aggressive action to confirm or rule out a diagnosis of cancer was acknowledged as a significant weakness in the defense of this case. Due to the uncertainty of a jury trial, this case was settled on behalf of the internal medicine physician.

This case study describes a scenario often seen in claims alleging failure to diagnose lung cancer. National and TMLT claim data reveal that failure to diagnose lung cancer is a significant professional liability concern. These claims typically involve the following issues, which demonstrate the need to improve patient care and reduce physician liability:

- misinterpretation or failure to recognize positive chest x-rays;
- failure to follow up on positive chest x-rays;
- suspicious or incidental findings not communicated to the primary care physician and no follow up occurs;
- physicians either missing symptoms or attributing them to another cause; and
- inadequate history taking.

Lung cancer

Lung cancer is the leading cause of cancer-related death in the United States. In 2004 lung cancer caused 160,440 deaths, compared to 127,210 deaths from colorectal, breast and prostate cancers over the same period. The estimated number of new lung cancer cases in 2004 was 173,770.¹

The one-year relative survival rate for lung cancer was 42% in 2000, up from 37% in 1975. This increase has been attributed to improvements in surgical techniques and combined therapies. The five-year relative survival rate for all stages combined is 15%. This increases to

49% for cases detected when the disease is localized; but only 16% of cases are diagnosed at this stage.²

Lung cancer is the most preventable cancer, with 87% of cases caused by tobacco smoke. The risk of lung cancer increases proportionally with the total number of cigarettes smoked. Smoking history is generally measured in pack-years, and physicians are encouraged to track their patients’ pack-years.³

Other risk factors for contracting lung cancer include:

- non-smokers’ exposure to secondhand smoke;
- occupational or environmental exposure to substances such as arsenic, vinyl chloride, nickel chromates, coal products, mustard gas and chloromethyl ethers, gasoline, diesel exhaust, benzene, asbestos, and radon;
- radiation exposure from occupational, medical and environmental sources;
- air pollution;
- recurring inflammation, resulting in scars left on the lungs from tuberculosis and some types of pneumonia; and
- family history of lung cancer.²

There are two major types of lung cancer. Approximately 13% of cancers are small-cell lung cancers (SCLC). This type of cancer tends to metastasize early and widely, and is almost always associated with smoking. The remaining 80% of lung cancers are non-small-cell lung cancer (NSCLC). The three subtypes in this group include squamous cell carcinoma, adenocarcinoma and large-cell undifferentiated carcinoma. Squamous cell carcinoma represents 25% to 30% of all lung cancers, and is usually associated with smoking history. Adenocarcinoma accounts for about 40% of lung cancers. It is slow growing and can be treated if found early. It is the most common subtype of lung cancer in women and nonsmokers. Large-cell undifferentiated carcinoma, accounts for 10% to 15% of lung cancers, grows and spreads rapidly.²

The most common symptoms of lung cancer include:

- persistent cough (in smokers with chronic bronchitis, a change in the character of the cough may indicate lung cancer);
- chest pain aggravated by deep breathing;
- hoarseness;
- weight loss and loss of appetite;
- hemoptysis;
- dyspnea;
- recurring bronchitis or pneumonia; and
- new onset of wheezing.²

“Symptoms of lung cancer usually do not appear until the disease is in an advanced stage. However, some lung cancers are diagnosed early because they are found in tests performed for other medical conditions. This is a particularly important point from a risk management perspective, as it reinforces the need for physicians to act upon an incidental finding that is suspicious of lung cancer.”⁴

Claim experience

In an analysis of national closed claims data from 1985 to 2003, the PIAA (a trade association of more than 60 liability insurance companies that insure approximately 60% of physicians, dentists, hospitals, and other health care professionals) found lung cancer was the

eighth most frequent condition generating medical liability claims. Of the 2,116 lung cancer claims reported to the PIAA, diagnostic errors were cited in 57.3%.³

“The data reported confirm the difficulties in diagnosing lung cancer. The presenting symptoms are often subtle and confusing. Symptoms of other illnesses, such as upper respiratory infections, are often present and can further complicate the practitioner’s ability to distinguish signs of lung cancer. Patients contracting this disease can have pronounced symptoms or very few.”³

In 2005, the PIAA released an updated *Lung Cancer Claims Study* that closely evaluates data from 184 paid claims arising from failure to diagnose lung cancer. These claims were closed between January 1, 1985 and June 30, 2004. The major findings include:

- The top three medical specialties involved in failure-to-diagnose lung cancer cases were: radiology (74 cases); internal medicine (45 cases); and family practice (45 cases).

- In 38% of cases there was no common presenting symptom, but rather an incidental, positive finding on x-ray. In 46% of cases the initial examination revealed no finding suggestive of lung cancer.

- In 150 cases, a chest x-ray was performed before the patient sought treatment for the ultimate diagnosis of lung cancer. These prior films were reviewed in 106 of 150 cases. A retrospective look indicates that these prior films were suggestive of cancer in 85% of cases. The average interval between the x-ray and the ultimate diagnosis of lung cancer was 13.7 months.

- A positive history of smoking was determined in 85% of the patients. The average number of pack-years reported was 38.7, with women reportedly having an average of 7 fewer pack-years than men.

- The presence of cancer in these cases was most often diagnosed in the last stage of metastasis (44% of determinable cases.)

- Communication issues were the most prevalent reason for a delay in diagnosis, reported in 52.6% of cases. Failure to respond to an abnormal x-ray was reported in 45.7% of cases.³ (*A closed claim study addressing several of these issues can be found on page 15.*)

Screening for lung cancer

Screening tests are a fundamental part of medical practice. Some tests, such as colonoscopy and Papanicolaou (Pap) tests, are considered quite effective in reducing morbidity and mortality of those diseases for which the tests were designed. Other screening tests, such as the prostate-specific antigen (PSA), are surrounded by uncertainty as to their efficacy in reducing morbidity and mortality. This uncertainty is reflected in the differing recommendations from professional organizations regarding PSA testing.⁵ With regard to lung cancer, no major organization that formulates public policy currently recommends screening for it. Lung cancer screening is not a routine practice for the general public or even for people who are at increased risk, such as smokers.⁶

“Studies of screening for lung cancer have been conducted in different populations using a range of modalities, including plain chest radiographs, sputum cytology, and computed tomography. Despite the fact that lung cancer is a common and lethal disease for which a major risk factor has been identified, no screening strategy has been unequivocally demonstrated to

PIAA Lung Cancer Claims Study 1985-2004

Delay in diagnosis

Reason for delay in diagnosis	Number of cases	Average indemnity
Communication	100	\$373,530
Failure to respond — abnormal x-ray	84	\$348,643
Inadequate follow-up	59	\$407,687
Confusion with other diseases	52	\$366,125
Inadequate initial evaluation	37	\$584,059
Late or no referral	27	\$387,130
Inadequate lab studies	25	\$403,760
Failure to obtain old films	15	\$264,167
Other*	37	\$460,142

*primarily misread or failure to order diagnostic imaging studies

Claims by physician specialty

Specialty	Number of cases	Average specialty indemnity
Radiology	74	\$328,038
Internal medicine	45	\$404,157
Family practice	45	\$212,737
Other surgical specialty	13	\$28,077
Pulmonology	12	\$279,708
General surgery	11	\$158,409
Cardiology	8	\$233,188
Emergency medicine	6	\$120,833
Vascular and thoracic surgery	4	\$443,231
Other nonsurgical specialty	12	\$229,750
Physician/group/corporation	24	\$261,927
Hospital	14	\$297,304

reduce mortality. For this reason, no major advisory organization recommends screening for lung cancer at the present time.”⁶

“However, critical reappraisal and long-term results from previous studies and early data from large ongoing trials have led to renewed clinical (and public) interest in screening for lung cancer, particularly using low-dose thoracic computed tomography. Although a reduction in mortality has not been demonstrated, significant advantages in stage distribution, resectability, survival, and fatality have been shown.”⁶

The most recent recommendations regarding lung cancer screening come from the U.S. Preventive Services Task Force. In 2004 it concluded, “the evidence is insufficient to recommend for or against screening asymptomatic persons for lung cancer with either low dose computed tomography, chest x-ray, sputum cytology or a combination of these tests. The Task Force found fair evidence that screening with any of these methods can detect lung cancer at an earlier stage than it would be detected in an unscreened population. However, it

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found poor evidence that any screening strategy decreased death rates from the disease. Because of the invasive nature of diagnostic testing and the possibility of a high number of false-positive tests (tests that indicate cancer where there is none) in certain populations, there is also the potential for significant harm from screening.”⁷

The National Lung Screening Trial, a clinical trial funded by the National Cancer Institute, was launched in 2002 to determine if screening individuals at high risk for lung cancer with spiral CT or with standard chest x-rays can reduce lung cancer deaths. The trial, with nearly 50,000 current or former smokers enrolled, will collect and analyze data for eight years.⁸

Although there is no definitive proof that early diagnosis of lung cancer changes mortality, lawsuits are still being filed — and indemnity payments are being made — as a result of alleged harm from failure to diagnose lung cancer. “While the biology of lung cancer so far disproves the value of lung cancer screening, physicians can be successfully sued anyway for failing to diagnose asymptomatic lung cancer,” says Jane Holeman, vice president of risk management.

The source of many of these lawsuits is the mismanagement of abnormal x-rays. “Lung cancer that is diagnosed incidentally is no different from lung cancer that is diagnosed from a screening test in terms of mortality. In most of these cases it is not about a medical issue, but about a legal or risk management issue such as failure to follow up or failure to communicate,” says Holeman.

Risk management considerations

“Right now, there is little agreement in the medical literature on the best way to diagnose lung cancer, and routine screening does not appear to help. While patients contribute to the development of this disease in a great number of cases, physicians must be diligent in communicating and documenting patient history, symptoms, and observations, and in addressing abnormal x-rays,” says Holeman.

Physicians can consider the following guidelines to help reduce liability in the area of diagnosing lung cancer.

- Document completely all patient complaints, events, and observations as well as the timeline and recommendations for subsequent diagnostic studies and follow-up treatment. Record information in a timely and accurate manner.
- Maintain a high index of suspicion when evaluating patients who report significant smoking history — more than 10 pack-years.
- Educate patients on the risks of smoking and encourage smoking cessation.
- Evaluate, refer and/or admit a patient presenting with any symptoms indicative of lung cancer until this diagnosis has been ruled out.
- If respiratory symptoms top the list of patient complaints, ask about possible exposure to other toxic substances known to increase the risk of respiratory problems or lung cancer.
- The use of screening chest x-rays and spiral CT scans is not supported in the medical literature and are not always medically indicated. However, the PIAA *Lung Cancer Claims Study* recommends that physicians consider screening tests for patients who are at high-risk.

“Those physicians who choose to screen their patients will experience the same potential benefits (finding an early lung cancer) and the same potential risks of malpractice litigation (increased chance for missed diagnoses, and false-positive workups that may lead to medical complications) as early 20th century physicians did when x-rays were first introduced. Once again, physicians must carefully balance the benefits and harms of new technologies, not only for their patients, but also for themselves.”⁹

- Routinely follow up with other physician consultants regarding test results. Consider the use of a follow-up tracking system to facilitate this process. Timely review and appropriate follow-up on all patient reports (lab, imaging, other diagnostic tests, or reports from consultants) is a prudent practice protocol. The ordering/referring physician has this responsibility and allowing reports to be filed in the patient’s record without review is difficult to defend. Physicians are encouraged to write their initials, the date of review and orders for follow-up on the reports to verify their actions. Review non-urgent test findings with patients at their next scheduled appointment, and document this discussion in the medical record.

- To reduce risk, physicians may need to make an extra effort to document a patient’s non-compliance or failure to follow up.

- Losing track of a patient who requires continuity of care, particularly in response to any abnormal report, places a physician at risk. Rather than advising the patient to “return to the clinic in the near future,” give the patient a scheduled appointment. That patient is then on the schedule and if the appointment is not kept, he/she can be contacted and this action documented in the medical record.

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ethics exchange

Disagreements between caregivers and families about end-of-life care

compiled and edited by Howard Marcus, MD

This article is the second in a series of articles featured in the Reporter addressing the ethical concerns of physicians. "Ethics exchange" will present an actual case and will analyze the issues by soliciting the opinions of experts in health law and medical ethics. The opinions expressed in "Ethics exchange" reflect the views of the authors and do not constitute official policy statements of Texas Medical Liability Trust.

Readers are invited to submit their own cases involving an ethical dilemma for consideration and publication in "Ethics exchange." Cases can be sent to laura-brockway@tmlt.org. The names, addresses, and affiliations of individuals whose cases are used will not be published.

The Terri Schiavo case in Florida illustrated a controversy that can arise when family members disagree over whether or not to continue life support. Similar conflicts and disagreements may also occur between family members and medical institutions, as recently occurred in Texas. In this Houston case a Texas statute that passed in 1999 provides a legal resolution for these extraordinarily difficult issues.

By Russell Hoverman, MD, PhD, hematology/oncology, medical ethics, in Austin

According to media accounts, Spiro Nikolouzos, 68, suffered brain damage in a motor vehicle accident more than 10 years ago. Since 2001 he has been in a persistent vegetative state. He was cared for in his home by his wife from 2001 until February 10, 2005, when he began to have bleeding around the gastrostomy feeding tube. He deteriorated rapidly and was placed on a ventilator in the emergency department at St. Luke's Hospital in Houston.

Independent tests by four neurologists indicated Nikolouzos' brain activity was severely compromised. St. Luke's followed the procedures of Texas law and informed the patient's family that the hospital was no longer obliged to provide medical support for Nikolouzos. The family would need to find this support elsewhere within ten days, after which time the hospital could withdraw

the respirator and artificial nutrition. The 21-member hospital ethics committee had reviewed the case and concluded that continued support would be unethical, inhumane and medically futile, and that support could be withdrawn.

St. Luke's based their action on the Texas Directive to Physicians Act passed by the Texas legislature in 1999. In 1996, Halevy and Brody published the results of the deliberations of the Houston Bioethics Network, a consortium of leaders from major Houston health care institutions.¹ A principal conclusion of the task force was that "the values of professional and institutional integrity should be recognized as grounding a prohibition on patients and families (from) forcing clinicians and institutions to provide treatments they judge to be inappropriate."

By the time this paper appeared, most large medical institutions had seen cases characterized by the consumption of enormous resources to no apparent benefit. The strength of this conclusion was affected by the changes made in the Texas statute of 1999 and which became an issue in the Nikolouzos case.

The statute supports the "institutional integrity" of the hospital and the medical profession. A hospital such as St. Luke's is guided by a mission to provide benefit to its patients in terms of improving health. The hospital is perpetuated by its ability to fulfill this mission. An institution in its own way has autonomy, just as a patient does. It has decision capacity and it has resources. In summary, a hospital has a value which carries weight against competing claims. Some of this value may be measured in economic terms. It is, after all, economic constraints that have made the Nikolouzos case so difficult. The family cannot afford to treat him at home, and it is not clear that any institution can afford to continue his treatment. It is, in the end, economics that determine how much medical care can be given to any population.

When there are competing claims in our society, either individuals versus individuals or institutions versus individuals, or some combination, there are public forums for

deciding a fair adjudication of the conflict. In the case of the conflict between institutions and families, the matter is addressed in the Texas Directive to Physicians Act. When the possibility of a patient returning to any level of consciousness is nil, the Act provides a mechanism for the value of the institution to take precedence over the family's wishes.

By Celeste Lira, RN, JD, health law attorney and partner with the law firm of Brin & Brin, PC, in San Antonio

The heart of the Nikolouzos controversy involves a state law which permits a health care facility to terminate the life-sustaining treatment of a patient, even against the wishes of family members, when the attending physician and the hospital have determined that further care is inappropriate. This law raises important questions. Have the rules regarding end-of-life care decisions changed? Has your hospital implemented a "futile care" policy?

Laws pertaining to right-to-life issues had, of course, existed in Texas before the 1999 legislative session. These laws include the Texas Statutory Advance Medical Directive, a legal document designed to communicate a patient's wishes about future medical treatment to physicians, families or surrogates. This law asks that the patient consider what burdens or hardships of treatment he would be willing to accept for a particular amount of benefit obtained if he were seriously ill. Through this statute the patient is also encouraged to discuss personal values and wishes with his family and physician.

In addition to this advance directive, Texas law provides for two other types of directives that can be important during serious illness — the medical power of attorney and the out-of-hospital do-not-resuscitate order. A medical power of attorney is used if an adult patient has not executed a directive and becomes incompetent or otherwise mentally or physically incapable of communication. The attending physician and the patient's legal

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Treating nursing home patients evaluating and limiting risk



Objectives

At the conclusion of this activity, the physician will be able to:

1. List state regulatory requirements for long-term care facilities specific to the treating physician.
2. Identify the top causes of nursing home litigation.
3. Discuss the regulatory requirements specific to the prescription of psychoactive medication.
4. Describe risk management strategies that address areas of liability.

Course author

Louise Walling is a risk management representative at TMLT.

Disclosure

Louise Walling has no commercial affiliations/interests to disclose related to this activity.

Target audience

This one-hour activity is intended for physicians of all specialties who are interested in practical ways to reduce the potential for malpractice liability.

CME credit statement

TMLT is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

TMLT designates this educational activity for a maximum of 1 category 1 credit toward the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

Ethics statement

This course has been designated by TMLT for 1 hour of education in medical ethics and/or professional responsibility.

Directions

Please read the entire article and answer the CME test questions. In order to receive credit, submit the completed test and evaluation form to TMLT. All test questions must be completed. Please print your name and address clearly. Allow four to six weeks from receipt of test and evaluation form for delivery of certificate.

Estimated time to complete activity

It should take approximately one hour to read this article and complete the questions.

Release/review date

This activity is released on May 27, 2005, and expires on June 1, 2007. Please note this CME activity does not meet TMLT's discount criteria. Physicians completing this CME activity will not receive a premium discount.

Introduction

For most adults, the thought of requiring nursing home care seems remote. Projections indicate that as the baby boomers age, (those born between 1946 and 1964) the number of adults age 65 and older will grow from 35 million in 2000 to 71.5 million in 2030. The population of adults age 85 and older grew from more than 100,000 in 1900 to 4.2 million in 2000.¹ Statisticians say that by 2030, 10.8 million elderly Americans will need nursing home placement.² It is safe to conclude that the demand for long-term care will only rise.

Currently, people aged 85 or older are the heaviest users of long-term care. The elderly comprise 13% of our total population. By 2030 that number will rise to 20% — one in every five Americans.³ This number projects a burgeoning demand on health care costs and even more critically, health care workers. The conclusion can be made that the need for physicians willing to care for the geriatric population will expand, due to both increased life expectancy and the projected growth of the elderly population.

Physicians' liability in treating nursing home patients has not gone unrecognized. Press accounts abound of million dollar jury awards in nursing home negligence and medical malpractice cases. Since the need for physicians' care will not likely diminish, the better approach is to be aware of the inherent liabilities, the standards of care and the regulatory requirements. Only then can the risks be addressed with preventative strategies.

Nursing home claim data

The Physician Insurers Association of America, a trade association of more than 60 liability insurance companies, analyzed data from 1,035 nursing home closed claims reported from 1985 to 2001. The PIAA found that diagnosis error was the most frequent and expensive misadventure for nursing home claims. From 1985 to 1997, the average indemnity rose more than 63%, from \$211,679 to \$346,066. Defense expenses per indemnity dollar were 32 cents for all claims; for nursing home claims it was nearly twice that amount, 59.6 cents per indemnity dollar. Failure to supervise or monitor case was the second most frequent misadventure in all nursing home claims.⁴

The medical condition most often reported in nursing home claims was decubitus ulcers, followed by hip fractures, diabetes, stroke and other joint disorders.⁴

Nursing home licensing agencies require facilities to employ medical directors who are also at risk of being included in claims. Medical directors can be sued if they fail to intervene when an attending physician is not fulfilling his or her duty to a patient. For

this reason, nursing homes often have difficulties finding physicians to serve as medical directors.

According to the PIAA data, among physicians who most frequently serve as medical directors of nursing homes, 82%, are internists and general and family physicians. These two specialties each account for 37.1% of nursing home claims. The indemnity pattern for medical directors from these two specialties shows a difference of only 2.9% (\$70,605 for internal medicine and \$68,620 for general and family physicians). In all claims reported to the PIAA, the difference between average indemnity for the two specialties is nearly 30%. This may indicate that physicians are exposed to similar liability while serving as medical directors.⁴

A study published in the *Annals of Long-Term Care*, found that the top causes of nursing home litigation include pressure ulcers, malnutrition and dehydration, and injurious falls. Other outcomes that may lead to litigation include elopement, adverse drug events, burns from unsafe smoking practices, untreated or undiagnosed changes in a medical condition, and improper discharge. Claims of negligence can include the misuse of physical or chemical restraints, and violation of a resident's rights, such as failure to obtain informed consent.⁵

Nursing home regulations

The Omnibus Budget Reconciliation Act of 1987 (OBRA '87) established national minimum standards of care and rights for people living in certified nursing facilities. This act affected the way state regulatory inspectors approached their visits to nursing homes, and stated that the medical director is responsible for implementation of medical care policies and coordination of medical care in the facility.⁶

The Texas Department of Aging and Disability Services Nursing Facility Requirements for Licensure and Medicaid Certification outlines requirements for physicians treating nursing home patients. It is well worth the time for physicians treating nursing home patients to become familiar with these regulatory requirements.

For Medicaid-certified facilities and Medicare skilled nursing facilities:

1. A physician must personally approve in writing a recommendation that an individual be admitted to a facility.⁷

2. The clinical record for the resident must contain at admission or within 14 days, documentation of an initial medical evaluation, including history, physical examination, diagnoses and an estimate of discharge and rehabilitation potential, and documentation of an annual medical examination.⁸

3. The physician must review and/or revise and sign orders relating to the resident's total program of care, including medications and treatments, according to the visit schedule required.

4. The physician must write, sign, and date progress notes at each visit.⁹

5. The physician must visit the patient at least once every 30 days for the first 90 days after admission, and at least once every 60 days thereafter.

At the option of the physician, required visits in Medicare skilled nursing facilities, after the initial visit, may alternate between personal visits from the physician and visits by a delegate, physician assistant, nurse practitioner, or clinical nurse specialist.¹⁰

Closed claim studies

To more fully illustrate the reasons for litigation the following closed claim studies are presented.

Case 1 — failure to properly treat decubiti

Presentation and physician action

A 75-year-old woman was admitted to a nursing and rehabilitation center. Her medical history included pressure ulcers, diabetes, peripheral vascular disease, hypertension, left hemiparesis from a CVA, dementia, osteoporosis, neurogenic bladder, and renal dysfunction. During the first 11 days in the facility, decubiti involving her buttocks, coccyx and feet were noted. She was transferred to a hospital for treatment of her bedsores, and was released back to the nursing home a week later. At this point, the defendant assumed the patient's care while also serving as the facility's medical director.

Upon her return she was noted to have decubiti on her right knee, sacrum, and right buttock. Blisters were noted on her right foot on the 2nd and 4th toe and a blood blister on her left foot. Nearly a year later, a NG tube was placed for fluid and medication followed by the placement of a G-tube the next month.

During this period, laboratory values indicated developing renal failure, which worsened over the next two months. Nursing home records indicated lab values of panic level for renal failure were called in to the medical director. No new orders were documented. Two weeks later the patient was transferred to the hospital, upon the family's request, with admitting diagnoses of stage IV decubiti, dehydration, anemia, acute and chronic renal failure, gastrointestinal bleeding and diabetes. She died one month later.

Allegations

The plaintiffs alleged that the physician was negligent in properly treating the

patient's decubiti, allowing them to worsen. They also allege that he was negligent in failing to properly diagnose and treat the patient's renal failure, which combined with the decubiti, led to her death.

Legal implications

Unfortunately, the insured had little recollection of the patient or his treatment of her. The nursing home chart did not contain physician progress notes or wound care orders for more than a year while the patient was under his care. The defendant adamantly stated that the notes he wrote were lost by the nursing home. However, all other portions of the chart were complete.

The most damaging evidence in the medical record was the critical lab value with no response. The defendant denied he was called by the nursing home. Yet when he visited the patient 3 days later, with the lab report on the chart, no new orders were written to treat the renal failure.

Disposition

No experts were able to support the defendant in this case. The plaintiffs were able to retain expert testimony critical of the care. During mediation and after several hours of discussion, the case ultimately concluded in favor of the plaintiff.

Risk management considerations

Lack of documentation was a major weakness in this case. It is recommended that a physician maintain a chart independent from that kept at the nursing home, even when the physician is the director of the facility. Although it may be impossible or unnecessary to duplicate 100% of the chart, certainly documenting an initial history and physical, diagnoses and medication regimen is recommended. Since nursing home care involves the physician taking telephone calls while away from the facility, a process should be in place for keeping a

record of what was reported, what was discussed, and the oral orders given. This would offer evidence of care should there be a discrepancy between the nursing home and the physician. It would also be advantageous by not requiring the doctor to rely solely on memory.

When a change in the patient's condition is reported to the physician, some evidence of response is indicated. Since most elderly bed-bound patients are at high risk for skin breakdown, it is advised that measures addressing pressure sore risk be ordered. There were no notes in the record that indicated orders for adequate turning or repositioning, or for a pressure relieving mattress.

With non-healing wounds, a nutritional consult may be necessary. The physician should also be aware of the dietician's recommendations and evaluate them for compatibility with the patient's other conditions, such as diabetes or renal failure.

There may also be a critical time in the patient's course that the current facility cannot offer the level of care required to treat the condition. The physician may need to intervene and not rely on the nursing home. It is at this juncture that a higher level of care is accessed through a long-term acute care facility, an outpatient, or critical wound care facility. If this is not feasible, a referral for a wound care consult may be in order.

Inadequate documentation was an obstacle in the defense of the physician. Although the practice of keeping records is time consuming and cumbersome, it is one of the best ways to track the reports received via the telephone and the oral orders given. It also serves as a reminder when phone calls from the facility are received, and the physician does not recognize the patient's name.

Case 2 – Failure to supervise/monitor case *Clinical presentation and physician action*

A 70-year-old woman with a history of Parkinson's disease, dementia and congestive

heart disease was admitted to a nursing home. Her activities of daily living showed significant impairments, justifying the need for nursing home care. Early documentation in the medical record indicated the woman would not ask for assistance, and would sit in the wheelchair for hours not wanting to bother staff. A compression fracture of T-10 was diagnosed within two months of her nursing home stay. Although functional assessments showed periods of disorientation and forgetfulness, the attending physician's nurse practitioner (NP) documented the patient had good rehabilitation potential.

Within the second year of her stay, the patient became cyanotic and lost consciousness while being assisted to the bathroom. The physician's NP gave orders to transfer the patient to the local emergency department. Initial vital signs of BP 75/32; pulse 78; respirations 24; and temperature 96.0 were documented. The ED physician diagnosed the patient with dehydration, hypokalemia, and hypotension. She was given IV fluids and Dopamine to elevate her BP. Vital signs taken at time of ED discharge revealed a BP of 110/65; temperature 97.5; pulse 100; and respirations 20.

Two days later the patient was noted to have labored respirations and a faint, irregular pulse. Her BP revealed hypotension of 72/38. The NP was notified and instructed the patient be transported to the local ED. After the administration of IV fluids, the ED physician notified the defendant that vital signs had stabilized. The patient then returned to the nursing home.

The next morning the patient had increased respirations, dyspnea and a weak pulse. Family members were present and asked to speak with the patient's attending physician. Three attempts were made by the nursing staff to contact the physician, each within 30 minutes. Messages were left to call the nursing home. Nearly 30 minutes after the third attempt, the NP responded and gave oral orders for a stat CXR, EKG, and change in the antibiotic. Later in the day, the NP visited the patient and gave orders for additional lab work of CBC, CPK, CKMB and Troponin I. ASA was started daily. Lab results were reported to the NP that evening. No new orders were received.

At 3 a.m. the patient began complaining of pain and discomfort throughout her body. She was now on oxygen and in the Trendelenburg position. Vital signs remained fairly stable the next three hours until the physician was notified at 6 a.m. of the patient's faint pulse and blood pressure too weak to register. Both hands revealed cyanotic fingernail beds. He was also notified that the

Liability coverage

TMLT policyholders who treat nursing home patients should be aware that their policy *does* provide coverage for any direct patient care of nursing home residents. However, for those physicians serving as medical directors at a nursing home, their TMLT policy *does not* cover their administrative activities as medical director. This is an important distinction, and if a suit is filed, coverage will ultimately be determined after a thorough investigation by the TMLT Claims Department.

Physicians are advised to ask the nursing home administration about the coverage provided, retain a copy of the policy that specifies the administrative duties are covered, and retain an updated copy of the policy as it renews. A copy of this policy should also be provided to TMLT to retain in the policyholder's file.

patient was a full code status. The physician informed the nurse that he had discussed the patient's case with the ED physicians. Since they could not find anything wrong with the patient, he gave orders to not transfer the patient to the ED, but to keep her comfortable.

Shortly after the phone call, the patient became diaphoretic with labored breathing and a faint pulse. The patient was transferred to the ED. CPR was initiated, but the patient did not respond and she was pronounced dead. An autopsy showed cause of death as massive bilateral pulmonary emboli, originating from the pelvic veins.

Allegations

The plaintiffs alleged that the attending physician's NP was negligent in failing to react to signs and symptoms of a pulmonary embolism when lab studies confirmed such a finding. Further, it was alleged that the NP failed to notify the physician of changes in the patient's condition resulting in a delay in diagnosing and treating her PE which led to the patient's death.

Disposition

Each expert witness reviewing this case concluded that the NP failed to react to signs of a PE when the lab studies and EKG likely confirmed such a finding. Secondly, the experts agreed that the NP was negligent in his failure to alert the physician of the changes and the patient's downward spiral throughout the last four days of her life.

Risk management considerations

According to a survey of Texas trial attorneys practicing in the field of medical malpractice, the number one reason people file suit against their health care provider is perceived physician indifference.¹¹ The physician's lack of availability to the patient and the family was a factor listed in the family's allegations. Reason states that it is easier to file a claim against someone with whom one has had minimal contact or failed to establish trust. The primary reason why patients or their families choose not to sue their health care provider, even when there is an indication of medical negligence, is the patient/family does not want to jeopardize the relationship. They believe in the integrity of the doctor.

In this case there was no documentation in the medical record indicating a physician's visit during the last year of the patient's life. The expert witness for the defense listed this as one of the weaknesses of the case.

The lack of communication and coordination between the physician and the NP was an issue in this case. When an advanced

health practitioner chooses to work in a collaborative practice, there is a requirement to practice under the protocols established by the physician. The physician also incurs the responsibility to supervise, and is vicariously liable for the actions of the advanced health practitioner. Inadequate supervision or over-delegation of duties may be perceived as negligence with the NP practicing beyond his or her scope of practice. Failure to supervise is a frequent allegation in these cases.¹²

Case 3 — Failure to properly medicate

Clinical Presentation and physician action

A 73-year-old man was admitted to a nursing home with diagnoses of CHF, atrial fibrillation, fecal and urinary incontinence, and dementia with psychotic features. He was under the care of an attending physician. Two months after his admission, the patient was reportedly delusional and having conflicts with his roommates. After an evaluation by a physical rehabilitation physician, it was determined that the patient was not a good candidate for rehabilitation due to his moderate to severe dementia. Over two years, a cardiologist treated the patient for atrial fibrillation, prescribing Coumadin, Cordarone, Toprol XL and Clonazepam.

The next year the nurses' notes indicate the patient was combative, hitting, kicking and repeatedly attempted to leave the facility. Within the next three months the patient became increasingly hostile and disoriented. It was reported that the patient was found in a female patient's room and stated that she was his wife, and they owned the building. Within this period the attending physician prescribed the antipsychotic Mogan.

A short time later, during a transfer from a shower chair, the patient fell and fractured his left femur. He was treated with hip surgery at a nearby hospital and released to the nursing home. The patient was put on the narcotic Lortab for pain. Within one week the patient was again found on the floor. X-rays did not reveal any injury. The physician ordered a vest restraint to be worn while the patient was in bed. Four days later the patient fell and dislocated the left hip prosthesis.

A psychiatric consult was ordered. Another antipsychotic, Loxitane, was added and Mogan and Klonopin were continued. The psychiatrist also ordered a vest restraint. However, the patient removed the vest, fell, and once again dislocated his left hip. His hip was successfully reduced at the hospital.

During this time, the attending physician was monitoring the patient's anticoagulant therapy. After several weeks, the lab results indicated a low INR and the patient's Coumadin was increased from 2 mg to 2.5

mg daily. When the INR level registered 4.0, the patient suffered a GI bleed and was admitted to the hospital with ischemic colitis. This required a colon resection and a blood transfusion.

A few months later, the patient fell again injuring his shoulder, which required an additional hospitalization. After recovering from this incident, the patient transferred to a different nursing home and all psychoactive medications were discontinued. It was reported that his cognitive function improved.

Allegations

The plaintiffs alleged the attending physician was negligent in failing to respond appropriately to the cause of the patient's multiple falls, which in their expert's opinion was due to continued use of the antipsychotics Mogan, Loxitane, and Klonopin. The second area of negligence was failure to properly monitor the patient's anticoagulant therapy resulting in a GI bleed.

Disposition

Defense experts were concerned about the number of psychotropic medications the physician had prescribed. These medications were not effective in managing the patient's disoriented and agitated state. It was also during this time that the patient continued to suffer from multiple falls. It was later learned that after the patient was taken off all his psychotropic medications, his mental status improved.

Concerns were also expressed about the physician's management of the anticoagulant therapy. The elevated INR went unaddressed for approximately one week before the GI bleed.

After negotiations, this case was settled in favor of the plaintiff.

Risk management considerations

Anticoagulant therapy requires close monitoring and management. The PT/INR results are often communicated by phone or fax. Whether the nursing home staff failed to accurately report the patient's levels or the physician incorrectly prescribed is not known in this case. As stated earlier, it is recommended that treating physicians keep their own records and include any changes in the treatment plan.

Resident rights and psychoactive medication

Although no violations were reported in the accompanying closed claims, it is recommended that any physician treating nursing home patients be informed about the facility's Statement of Resident Rights. The Texas Department of Aging and Disability Services

has established this statement for all licensed and Medicaid-certified long-term nursing facilities. These include the right to:

- “retain the services of a physician of your choice, at your own expense or through a health care plan, and to have a physician explain to you, in language you understand, your complete medical condition, the recommended treatment, and the expected results of the treatment, including reasonably expected effects, side effects, and risks associated with psychoactive medications;
- be free from any physical or chemical restraints imposed for the purposes of discipline or convenience and not required to treat your medical systems;
- receive information about the prescribed psychoactive medication from the person who prescribes the medication or that person’s designee; to have any psychoactive medications prescribed and administered in a responsible manner, as mandated by the Health and Safety Code, Section 242.505; and
- refuse to consent to the prescription of psychoactive medications.”¹³

If the patient is not making his or her health care decisions, then the party designated as power of attorney for health care would require consultation. This is further clarified in the long-term nursing facility standards for prescription of psychoactive medication.

According to the Texas Department of Aging and Disability Services, consent for the prescription of psychoactive medication given by a nursing home resident, or by a person authorized by law to consent on behalf of the resident, is valid only if:

1. consent is given voluntarily and without coercive or undue influence;
2. the person who prescribes the medication, or that person’s designee, provides the resident and, if applicable, the person authorized by law on behalf of the resident, with the following information in a single document identified as being for the purpose of consent to treatment with psychoactive medication:
 - A. the specific condition to be treated;
 - B. the beneficial effects on that condition expected from the medication;
 - C. the probable clinically significant side effects and risks associated with the medication, as reported in widely available pharmacy databases or the manufacturer’s package insert; and
 - D. the proposed course of the medication;
3. the resident and, if appropriate, the person authorized by law to consent on behalf of the resident, are informed in writing that consent may be revoked; and
4. the consent is evidenced in the resident’s clinical record by a signed form pre-

scribed by the facility, or by a statement of the person who prescribes the medication or that person’s designee, that documents consent was given by the appropriate person and the circumstances under which the consent was obtained.

- A. Consent is valid until (i) consent is withdrawn; or (ii) the practitioner has discontinued the medication.
- B. For purposes of this rule, a medication will be considered to be discontinued if therapy has been suspended for more than 70 days. If the suspended therapy is resumed within the 70-day period, an oral explanation of side effects should be documented in the clinical record.”¹⁴

Conducting discovery

Nursing home claims generally fall into three categories: abuse, neglect, and property or fiduciary neglect cases. Aggressive attorneys search for issues in at least one if not all of these categories. It is the allegation of neglect that holds the greatest potential for liability for the physician. Allegations of neglect can arise from a number of incidents — pressure sore/decubitus ulcer formation, malnutrition, dehydration, contractures, infections, medication errors, a patient’s fall or if a patient is dropped or injured during physical transfers.

In building their case, plaintiffs’ attorneys will obtain and examine all medical records for charting errors and inconsistencies between a physician’s orders and implementation by the nursing staff. There may be requests made for all documented complaints involving mistreatment, abuse, neglect or injuries, and for complaints made by employees regarding abuse, neglect or injuries sustained by the residents of the nursing home. Incident reports and investigative reports completed by the nursing home may also be requested and examined.

In addition, all medical records generated by other health care providers for the patient will likely be obtained. This may include records from physicians, surgeons, therapists, hospitals, home health and ambulance services. Employees may be questioned concerning care and treatment of the resident, as well as the facility’s policies and procedures. During this time of discovery theories are built to support the claims of negligence.

With such scrutiny, physicians who treat nursing home patients can easily see the merit behind the recommendation to keep their own medical records on each nursing home patient.

Conclusion

The need for physicians to treat nursing home patients can only increase as the geriatric population grows. With effective risk management practices in place, a physician is better prepared for the challenges he or she will face when treating nursing home patients. Patients will also benefit through improved quality of care, which is the best defense against any malpractice litigation.

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mass litigation alert

Pitfalls in the prescription of medications for psychiatric disorders

by Jay H. Henderson, JD and Scott Allen, JD

Editor's note: Two TMLT defense attorneys with experience in mass litigation will discuss the legal environment surrounding the use of prescription medications to treat mental illness. The authors are partners in the law firm of Cruse, Scott, Henderson and Allen in Houston.

One of the most dynamic areas of legal medicine is identifying the guidelines to be followed in the use of psychiatric medications in adults and children. Consumer groups and the media continue to publicize dramatic incidents, including suicides, allegedly caused by the use of these drugs. Pharmaceutical companies, on the other hand, steadfastly deny rumors of corporate misbehavior and product-adverse events, and continue to depict their products as innocent bystanders in the fight against mental illnesses. The truth probably lies somewhere in between.

Prescription medications are an important tool in the treatment of many adult and adolescent patients with legitimate psychiatric disorders. The most common psychiatric disorder for which a prescription medication may be employed is depression. The American Psychiatric Association's *Practice Guideline for the Treatment of Patients with Major Depressive Disorder* supports the use of antidepressants, often as an adjunct to a multifaceted approach to treatment. Other psychiatric disorders, such as bipolar disorder, likewise require these medications in appropriate patients. The discussion recaps some of the key developments in this context during the past year.

2004 labeling change for antidepressants

In March 2004, the FDA announced that it was requiring a major labeling change for all antidepressant drugs, including Prozac (fluoxetine); Zoloft (sertraline); Paxil (paroxetine); Luvox (fluvoxamine); Celexa (citalopram); Lexapro (escitalopram); Wellbutrin (bupropion); Effexor (venlafaxine); Serzone (nefazodone); and Remeron (mirtazapine). The revised warning includes the following guidelines:

- "Health care providers should carefully monitor patients receiving antidepressants

for possible worsening of depression or suicidality, especially at the beginning of therapy or when the dose either increases or decreases. Although FDA has not concluded that these drugs cause worsening depression or suicidality, health care providers should be aware that worsening of symptoms could be due to the underlying disease or might be a result of drug therapy.

- Health care providers should carefully evaluate patients in whom depression persistently worsens, or emergent suicidality is severe, abrupt in onset, or was not part of the presenting symptoms, to determine what intervention, including discontinuing or modifying the current drug therapy, is indicated.

- Anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia (severe restlessness), hypomania, and mania have been reported in adult and pediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and non-psychiatric. Although FDA has not concluded that these symptoms are a precursor to either worsening of depression or the emergence of suicidal impulses, there is concern that patients who experience one or more of these symptoms may be at increased risk for worsening depression or suicidality. Therefore, therapy should be evaluated, and medications may need to be discontinued, when symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.

- If a decision is made to discontinue treatment, certain of these medications should be tapered rather than stopped abruptly (see labeling for individual drug products for details).

- Because antidepressants are believed to have the potential for inducing manic episodes in patients with bipolar disorder, there is a concern about using antidepressants alone in this population. Therefore, patients should be adequately screened to determine if they are at risk for bipolar disorder before initiating antidepressant treatment so that they can be appropriately monitored during treatment.

Such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression.

- Health care providers should instruct patients, their families and their caregivers to be alert for the emergence of agitation, irritability, and the other symptoms described above, as well as the emergence of suicidality and worsening depression, and to report such symptoms immediately to their health care provider."²

Many general and family practice physicians are called upon to prescribe antidepressants to their patients. These physicians may properly dispense these medications when the patient's diagnosis and treatment needs fall within their level of expertise. In some instances, however, psychiatric patients require the services of physicians trained in treating mental health disorders.

In those situations in which the primary care physician elects to treat patients with antidepressants, consideration of and documentation of compliance with relevant FDA guidelines will be of assistance when others review the records later, either in the furtherance of patient care or in the event of subsequent litigation. Patient selection, informed consent, and monitoring of prescription drug use are other areas in which careful documentation can be very useful.

While the physician's judgment must always be the guide in making prescribing decisions, the precarious legal environment surrounding the use of these drugs warrants substantial attention to documentation of the prescriber's thought process.

Use of antidepressants in adolescents and children

Of greatest interest recently has been the use of antidepressant medications in pediatric patients. In Fall 2004, the FDA announced the imposition of a black box warning regarding the use of antidepressants in children and adolescents. This black box warning, which is the strongest warning mandated by the FDA, states:

“Antidepressants increase the risk of suicidal thinking and behavior (suicidality) in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of [Drug Name] or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. [Drug Name] is not approved for use in pediatric patients except for patients with [Any approved pediatric uses here]. (See Warnings and Precautions: Pediatric Use)

Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of nine antidepressant drugs (SSRI's and others) in children and adolescents with MDD, obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events on drug was 4%, twice the placebo risk of 2%. No suicides occurred in these trials.”³

The FDA has also written a *Medication Guide about Using Antidepressants in Children or Teenagers*, available at www.fda.gov/cder/drug/antidepressants/MG_template.pdf. This guide focuses on the issue of increased risk of suicidality in children, and physicians are encouraged to use this tool in their consultation, prescription, and follow up with patients. While this is not a formal informed consent document, it would be beneficial, from a legal standpoint, to have the patient's parent or guardian sign a copy of the *Medication Guide* to acknowledge receipt of this information as a part of the informed consent process.

For more information about the use of antidepressants, consult www.fda.gov/cder/drug/antidepressants/default.htm.

Non-FDA approved uses

Physicians know that they are permitted to use any medication for any medically appropriate use. FDA consideration and approval are not required before a drug may be used “off label.” The term “off label use” is a misnomer, however, because “off label use” simply means that the FDA has not reviewed such use, so the insinuation that it is “unapproved” is misleading. In fact, certain non-FDA approved uses of medications often reflect mainstream medical practice.

Nonetheless, physicians are encouraged to maintain vigilance when using medications

for non-FDA approved uses. Just because a drug company, either through written communication, media, or via their sales force, says that a drug may be used for an indication, does not mean they will support such use in the event of litigation. Documenting each step of the process of diagnosis, indication, informed consent, patient assent, and follow-up care, particularly when a drug is prescribed for a use outside the terms of the product labeling, will help demonstrate sound decision-making and will assist physicians in defending their actions in the event of litigation.

In May 2004, Pfizer agreed to a fine of \$430 million after its subsidiary, Warner-Lambert, was accused of “off label” promotion of Neurontin. It is unsettled whether or not Neurontin, which is approved for epileptic disorders, is also a good drug for certain psychiatric disorders as was claimed by Warner Lambert. However, physicians should keep in mind that they will almost certainly not receive the support of the drug manufacturer if litigation arises from the use of a drug for a non-FDA approved use. In fact, they are more likely to see the drug company shift the blame to the physician as the party responsible for the selection of a drug for a particular patient. In addition, the drug companies will generally try to exonerate themselves by pointing out that the FDA did not approve the use for which their drug was prescribed, thereby attempting to break the “causal connection” between the pharmaceutical company and the patient.

The prudent physician will exercise independent judgment in selecting drugs for innovative uses. Primary care physicians should consider deferring to specialists when complex psychiatric disorders may require novel treatments. Physicians should also be cautious regarding the promotional techniques of pharmaceutical representatives which can be misleading. Even if a representative provides published medical articles that discuss non-FDA approved drug uses, physicians should consider carefully whether appropriate indications exist for using the drug for those purposes.

In the end, assuming there are alternative modes of treatment available, it is often safest to stick with the established treatment regimens as a first line treatment. If pharmaceutical representatives do provide articles or study results promoting their drugs, it would be prudent to date and preserve those, and document that they were provided by the pharmaceutical company representative.

Antipsychotics and diabetes

In March 2004, the FDA also imposed a labeling change for all atypical antipsychotic medications. The new warning describes an

increased risk of hyperglycemia and diabetes in patients taking these medications, which include Zyprexa, Clozaril, Risperdal, Seroquel, Geodon, and Abilify. Although the connection between these medications and hyperglycemic disorders is not completely understood, the warning states: “epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics.”⁴

The warning further indicates that diabetic patients should be “regularly” monitored for worsening of glucose control and that patients with risk factors for diabetes should be tested at the outset of treatment and “periodically” during treatment. These loose guidelines leave much to be interpreted, and are typical in that they leave patient care decisions open to individual physicians. This leaves an opening for the pharmaceutical company to shift blame to the physicians in the event problems occur.

Monitoring issues

Another issue that warrants attention is the role of the physician in monitoring patients who are being prescribed medication for a psychiatric condition. Monitoring is a patient-specific issue for which no “cookbook” guidelines can be provided. However, the *Medication Guide* referenced earlier includes a suggested schedule for post-prescription physician office visits. At first glance, this would appear to be a rigorous monitoring schedule. Nonetheless, in some instances, there are unique health issues to be considered.

For example, the product labeling for Zyprexa states: “Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment.”⁵

Undoubtedly, there are many instances in which the interpretation of this guideline would reasonably differ among physicians. More importantly, what is “right” for one patient is not always the best course of action for every patient. Consult with knowledgeable individuals and references in making a determination on patient monitoring and to implement the chosen monitoring policy in a consistent manner.

Atypical antipsychotic drugs

On April 11, 2005, the FDA issued a public health advisory on atypical antipsychotic medications. (See www.fda.gov/cder/drug/advisory/antipsychotics.htm.) The FDA talk paper that accompanied the advisory explains:

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The FDA “issued a public health advisory to alert health care providers, patients, and patient caregivers to new safety information concerning an unapproved (i.e., ‘off-label’) use of certain drugs called “atypical antipsychotic drugs.” These drugs are approved for the treatment of schizophrenia and mania, but clinical studies of these drugs to treat behavioral disorders in elderly patients with dementia have shown a higher death rate associated with their use compared to patients receiving a placebo (sugar pill).”⁶

Additional information, including a list of drugs to which this advisory applies, is available at: www.fda.gov/cder/drug/infopage/antipsychotics/default.htm.

Conclusion

This discussion provides ample evidence that the use of medication in the treatment of psychiatric disorders requires vigilance on the part of the prescribing physician. There have been significant legal and regulatory developments since 2004 that further affect this area of practice. From a legal standpoint, it is recommended that physicians document each step of their prescription and treatment process: patient selection, indications, informed consent, and monitoring. Use of informational tools, such as the FDA *Medication Guide*, is encouraged. Both physicians and patients will benefit from thorough scrutiny of the selection and use of these medications.

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Policy change to practice-based CME activity

Effective June 1, 2005, TMLT's practice-based CME activity, which is an optional component of the practice review, will be accredited for 1 hour of ethics CME, instead of the 2 hours that were previously offered. This will expedite the practice review process and still give the physician an opportunity to fulfill the 1 hour ethics CME licensure requirement.

In order to receive CME credit, the physician must first complete a self-assessment tool to identify areas of risk in the practice. Secondly, at the conclusion of the practice review, the physician must participate in a discussion with the risk management representative regarding identified areas of liability and recommended risk management interventions.

TMLT's practice review is offered at no cost to policyholders and takes place on a per-request basis. Physicians can receive a 3% discount for completing the process, following verification that review recommendations were met. An additional 2.5% discount is available if the physician has fully implemented electronic prescribing or electronic health records for a minimum of one year.

For more information, please contact Rebecca Deones at (800) 580-8658, ext 5912.



Earn 1 hour of ethics CME

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Learn to reduce your chances of being involved in a malpractice claim. Request a Practice Review and a TMLT risk management professional will visit your office to determine your risk exposure. Physicians completing the Practice Review can earn a 3 percent premium discount (after review recommendations are met) and 1 hour of ethics CME.

Practice reviews are free to all TMLT policyholders, and can be completed without disrupting patient appointments. Request a Practice Review at www.tmlt.org or call (800) 580-8658.

closed claim study

Delay in the diagnosis of lung cancer

by Barbara Rose and Laura Brockway

The following closed claim study is based on an actual malpractice claim from Texas Medical Liability Trust. This case illustrates how action or inaction on the part of physicians led to allegations of professional liability, and how risk management techniques may have either prevented the outcome or increased the physician's defensibility. The ultimate goal in presenting this case is to help physicians practice safe medicine. An attempt has been made to make the material less easy to identify. If you recognize your own claim, please be assured it is presented solely to emphasize the issues of the case.

Presentation

A 62-year-old man came to his family physician's office complaining of paresthesias and weakness. The patient had been under the care of the physician for three years and had a history of diabetes and hypertension. The medical records indicated he did not smoke or drink. The family physician referred the patient to a local emergency department.

Physician action

The ED physician suspected a stroke, and the patient was admitted under the care of a neurologist, the defendant in this case. The patient had suffered a cerebral infarction that resulted in left-sided hemiplegia. The neurologist evaluated the patient and found there were no x-ray reports on the chart. He initiated medical therapy for the stroke and ordered a chest x-ray if one had not already been done.

When he returned the next morning, the neurologist examined the patient and reviewed his chart. The chart now included a chest x-ray report describing an ill-defined infiltrate of the right lobe and recommended a follow-up study. The neurologist further reviewed the chart and found a second chest x-ray report, this one describing a clear field. The neurologist was satisfied with the lung assessment, and concluded that the second chest x-ray report was the one he had ordered. He was not surprised by the appearance of a second chest film report even though he had not specifically ordered a

follow-up chest film. The neurologist assumed the ward clerk or nurse was unaware of the original film and obtained a second in response to his written order to obtain a chest x-ray if one had not been done. The neurologist made reference to the second chest film in his discharge summary.

After six days in the hospital, the patient was discharged to a rehabilitation facility. The patient recovered use of his left leg, but continued to have paralysis in the left arm. He required speech, physical, and occupational therapy as well as psychological support.

Approximately 18 months after the stroke, the patient developed a cough and difficulty breathing. A chest x-ray revealed a moderate-sized right pleural effusion. He underwent a thoracentesis with withdrawal of more than one liter of bloody fluid. A second procedure a month later led to a pathological evaluation for suspicion of malignancy. The patient was found to have a soft tissue mass of 2.2 cm, confirmed to be a metastatic adenocarcinoma consistent with the lung as the primary site. The patient underwent chemotherapy, but died one year later.

Allegations

In their lawsuit against the neurologist and the hospital, the patient's family alleged delay in the diagnosis of lung cancer. Learning that the lawsuit involved lung cancer, the neurologist reviewed a copy of the patient's hospital record, and learned for the first time that the follow-up chest x-ray that showed a clear lung field referred to a different patient.

Legal implications

It was clear that the neurologist relied on the "clear lung field" report of a different patient and did not resolve the suspicion raised by the first x-ray. The plaintiff's oncology expert claimed the cancer was either stage I or early stage II at the time of the hospital x-ray with a probable five-year survival rate of 30%. When the correct diagnosis was made, the patient's five-year survival rate was less than 1%.

The plaintiff's neurology expert testified that the defendant breached the standard of care by failing to recognize the name on the x-ray report was not his patient's. However, he also testified that when a physician picks up a hospital chart, it is reasonable to anticipate that the documents in the chart belong to the patient. He agreed that the vast majority of reports found in medical charts are properly filed.

At his deposition, the defense neurology expert testified that while not favorable, the wrong report can make it into a physician's hands unnoticed without the physician being negligent. All defense consultants who reviewed the medical records in this case failed to catch the misfiled x-ray report, as did the other physicians who treated the patient in the hospital.

This case was further complicated by a conflict with the codefendant hospital over responsibility for the error.

Disposition

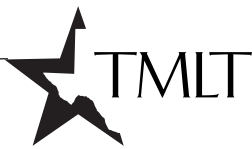
To avoid the uncertainties of a jury trial, this case was settled with the consent of the neurologist. The hospital also settled with the plaintiff.

Risk management considerations

Responsibility is to be shared in the events of this case. A hospital employee filed a negative chest x-ray report in the wrong medical record. Compound that mistake with the physician's review of the report and failure to note it was a different patient. When reviewing reports in hospital charts many physicians, including the defendant, focus on the results and not the name on the report. As this case demonstrates, physicians may be well advised to take that extra step and verify the name on the report. Failure to do so can have disastrous consequences. Likewise, the hospital has hopefully examined its procedures and staff responsibilities to prevent this from occurring again.

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guardian, or an agent, may then use a medical power of attorney to make treatment decisions including the decision to withhold or withdraw life-sustaining treatment from the patient. In the instance where the patient has not executed a medical power of attorney, the attending physician may make a treatment decision on behalf of the patient to withhold or withdraw life-sustaining treatment, and he or she makes this decision in conjunction with one of the following persons in order of priority:

1. the patient's spouse;
2. the patient's reasonably available adult children;
3. the patient's parent; or
4. the patient's nearest living relative.

As in the Nikolouzos case, there is the possibility that the patient's or family's wishes will be in conflict with those of the physician. The 1999 law clarifies the physician's and institution's roles. Thus, Texas law allows a health care professional and institution to, in effect, overrule the patient or family. If a

physician determines that continued life sustaining care is inappropriate for a patient, Texas law allows the physician to request a hearing before the hospital ethics committee for a final determination.

Mrs. Nikolouzos petitioned the hospital ethics committee to prolong her husband's stay and allow him to continue on life support equipment. However, because the ethics committee determined that the financial burden to the institution outweighed the potential benefits to Nikolouzos, the family was given ten days to find another institution willing to accept the patient. Mrs. Nikolouzos sought a temporary restraining order requiring the hospital to continue treating her husband until she could locate another health care facility to accept him, but the court denied her request even though as the court pointed out in its opinion that "... under this unique Texas statutory scheme, already bereaved families are left with limited procedures to secure alternate care for their loved one." Ultimately Mrs. Nikolouzos was able to find a facility in San Antonio that would admit her husband.

The Texas Advance Directives Act brings many important benefits to patients, families, physicians, and medical institutions. These are discussed elsewhere in the medical literature. (Please see web sites listed below.) Licensing authorities can penalize both physicians and nurses if a proper process is not followed. In addition, immunity from civil and criminal prosecution after ignoring the wishes of a surrogate health care decision-maker is offered only if the ethics consultation process is followed.

For more information, please consult www.healthcouncil.org/publications/futility.html and www.baylorhealth.edu/proceedings/13_2/13_2_fine.html.

Sources

1. Halevy A, Brody BA. A multi-institution collaborative policy on medical futility. *JAMA*. 276: 571-574.

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